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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/747,996	12/29/2003	Yung-Ming Chen	50623.328	6554

7590 12/12/2007

Cameron Kerrigan
Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111

EXAMINER	
EDWARDS, LAURA ESTELLE	
ART UNIT	PAPER NUMBER
1792	

MAIL DATE	DELIVERY MODE
12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/747,996	CHEN ET AL.	
	Examiner	Art Unit	
	Laura Edwards	1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *25-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24 and 34-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

Claim 1-4, 10, 12, 13, 21-24, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by XP-0009807 for reasons cited in the previous office action.

New claim 39 still reads on the claimed invention because the applicator has a coating surface which comes in contact with the implant device or stent and the coating and the applicator is porous.

Claim Rejections - 35 USC § 103

Claims 5, 6, 8, 9, 14-20, 34-38, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over XP-000980708 for reasons set forth in the previous office action.

With respect to claims 34-37, the characteristics of the applicator from including uniform pores to the applicator having filaments or capillaries goes to the characteristics of the foam or cloth. Such characteristics of the applicator would be well within the purview of one skilled in the art so as to control the amount of coating material to be applied and retained on the medical implant device.

With respect to claim 38, with the applicator being soaked or saturated with coating material, one of ordinary skill in the art would expect drainage or an excess of coating material to be retained in the bottom of the reservoir.

With respect to claim 40, while the reservoir used is a cylindrical shaped cup, one of ordinary skill in the art would readily appreciate the reservoir being of any shape including a square or rectangle and so forth. The latter case would result in a shallow pan wherein less applicator material would be required to coat the implant device. The latter case would also

require the implant device to be coat via horizontal manipulation with the coating surface to some degree being above the base of the reservoir.

Response to Arguments

Applicants' arguments filed 9/21/07 have been fully considered but they are not persuasive.

Applicants contend that Claim 1 is not anticipated by XP because XP does not teach or suggest an applicator including a coating surface and a porous region in fluid communication with a coating composition in a reservoir, wherein the porous region is capable of conveying the coating composition from the reservoir to the coating surface. XP discloses an agent soaked sponge for coating a stent. Being that the carrier (C) is soaked, it would not be capable of conveying a composition from a reservoir to a coating surface. This argument is not deemed persuasive because the wicking action of the applicator material and the outermost surface of the applicator coming in contact with the implant device would transfer coating to the implant device. Excess material drained in the bottom of the reservoir would, over time, wick up the applicator and be transferred to the implant device. XP remains to anticipate the claimed invention.

Applicants contend that the XP reference does not teach a half-tubular body configured to receive the device. This argument is not deemed persuasive because the recited claim language would not exclude the tubular body or mandrel taught by the XP reference because no explicit length of dimension of the tubular body to constitute a half body is set forth.

Dependent Claims 14 and 17 refer to a system that includes an additional component: a pressure apparatus or pressurizing device, respectively. This argument is well taken, in that there is no structural pressure device other than that which would be used by the user's hands. Regardless, it would be common sense to use pressure when coating the implant device in instances wherein the applicator is less saturated or void of excess coating material.

Information Disclosure Statement

Applicants cited the XP-000980708 reference relied upon in the above rejection. A copy of it has been attached to the present office action.

The Examiner has reviewed the application(s) cited by Applicants on the IDS. The serial number(s) has been crossed out such that the cited application(s) would not appear on the face of a patent in the event that the present application goes to issue.

Conclusion

Applicant's amendment necessitated the new grounds) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nadine Norton can be reached on (571) 272-1465. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura Edwards
Primary Examiner
Art Unit 1792

December 10, 2007

CH V2244

XP-000980708 pgs = (2)

434009

Rolling therapeutic agent loading device for therapeutic agent delivery or coated stent p.d. 06-2000

Stents are typically implanted within a vessel to maintain vessel integrity in order to allow fluid flow through the vessel. Balloon catheters are often utilized to implant the stent in the vessel. These devices as well as other devices used in body passageways can be coated with a pharmacologically active substance for either short or long term local delivery to the passageway. The method described can be used for loading a therapeutic agent onto a device used in a blood vessel.

In this process, as shown in Fig. 1, an anchoring fixture, such as a spiral mandrel or a hypotube (A) is securely fitted and inserted into a vessel device (B), such as, but not limited to, a stent. This will secure the vessel device on the anchoring fixture during the therapeutic agent loading process. The device (B) is pre-coated with a swell-loading or therapeutic agent specific "binding" polymer. By rolling the stent on a carrier (C) such as, but not limited to, a cloth or sponge, soaked with either a therapeutic agent solution or a tacky therapeutic agent paste (D); the therapeutic agent is loaded into the polymer.

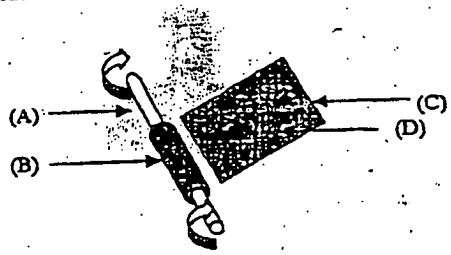

Fig. 1

When the operator loads the therapeutic agent solution or tacky paste (D) onto the vessel device (B), the vessel device (B) mounted on the anchoring fixture (A) is rotated forward on either a therapeutic agent soaked carrier (C and D) or a tacky therapeutic agent paste (D). In the embodiment using the tacky therapeutic agent paste (D), a binding agent can be added to the raw therapeutic agent material to cause adhesion of the therapeutic agent powder particles. This anchoring fixture (A) and method will allow the cardiologist to load therapeutic agent solution or tacky therapeutic agent paste (D) onto the vessel device (B) prior to deployment into the patient. This method eliminates the complexity of preloaded therapeutic agent delivery devices, such as stents. This invention allows the cardiologist the freedom to choose whichever therapeutic agent thought to be beneficial to the patient.

The anchoring device (A) may be made from any number of materials. Examples include, but are not limited to, polytetrafluoroethylene (PTFE), polypropylene, polymethylmethacrylate (PMMA), stainless steel or glass. The swell loading or therapeutic agent specific "binding" polymer which is precoated onto the device (B) may include, but is not limited to, the following: polyethyleneglycol (PEG), hydroxyethylmethacrylate (HEMA),

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polyvinylpyrrolidone (PVP), x-linked hyaluronic acid based hydrogels for swell loading; polycarprolactone (PCL), polylactic acid (PLA), polyglycolic acid (PGA), and copolymers thereof, biopolymers, elastin, or collagen elastin. The therapeutic agent solution or tacky therapeutic agent paste (D) may consist of, but are not limited to the following: therapeutic agent in a single suspension, single solution, or in solution with a polymer that acts as a matrix. Possible polymers and copolymer components include, but are not limited to the following: ethylene vinyl alcohol (EVAL) and polyurethanes.

In an alternative embodiment as shown in Fig. 2, the therapeutic agent solution (D) can be loaded onto the vessel device (B) by rotating the anchoring fixture (A), on which the vessel device (B) is secured onto, in a cylindrical cup (E) filled with therapeutic agent solution. The cup is lined with a carrier (C) such as, but not limited to, a sponge or foam type material soaked with therapeutic agent solution (D). The vessel device (B) is rolled along the inside wall of the therapeutic agent (D) soaked carrier (C) thereby loading the vessel device (B) with the therapeutic agent solution(D). The cup (E) may be made from any non-reactive substance such as, but not limited to, plastic or glass.

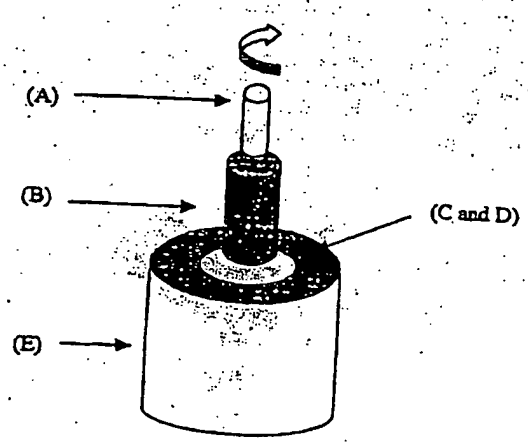

Fig. 2

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